UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

KIMMY McNAIR and
LARRY McNAIR,

Plaintiffs,

v. **Civil Action No. 2:14-17463**

JOHNSON & JOHNSON,
a foreign corporation, and
JANSSEN PHARMACEUTICALS, INC.,
a foreign corporation, and
ORTHO-McNEIL PHARMACEUTICAL, INC.,
a foreign corporation,

Defendants.

MEMORANDUM OPINION & ORDER

Pending is the defendants' motion for summary judgment, filed December 10, 2014.

I. Background

Kimmy and Larry McNair are a married couple from Charleston, West Virginia. In March of 2012, Kimmy fell ill and sought treatment from Dr. Lisa Downham at the HealthPlus Urgent Care Center. Dr. Downham diagnosed Kimmy with pneumonia and prescribed a course of Levaquin.

Levaquin is a trademarked brand of the antibiotic generically known as levofloxacin. Ortho-McNeil Pharm. v. Lupin

Pharms., 603 F.3d 1377, 1377-39 (Fed. Cir. 2010) (noting that the Food and Drug Administration "approved levofloxacin for commercial marketing and use as the product having the brand name Levaquin" in 1996). Levofloxacin's inventor obtained a patent for the drug which it exclusively licensed to one of the defendants, Ortho-McNeil Pharmaceutical, Inc. ("Ortho"). Id. According to the defendants, all of Ortho's assets were transferred to Janssen Pharmaceuticals, Inc. ("JPI") on December 31, 2007. Johnson & Johnson is JPI's parent company. See Ortho-McNeil Pharm., Inc. v. Mylan Laboratories, Inc., 348 F. Supp. 2d 713, 719 (N.D. W. Va. 2004) (describing Johnson & Johnson as "the parent company of Ortho-McNeil Pharmaceutical, Inc. . . . which holds a license to distribute levofloxacin in the United States.").

Approximately one week after her visit with Dr. Downham, Kimmy "collapsed at work" and "was taken to Charleston Area Medical Center, Inc. [("CAMC")], where she was diagnosed with ARDS, was admitted, listed as critical care and had to be intubated."[1] Defendants' Motion for Summary Judgment ("Defs.' Mot."), Ex. 2 at 21. "Since the initial diagnosis of ARDS,

[1] "ARDS" is an acronym for Acute Respiratory Distress Syndrome, "a life-threatening lung condition that prevents enough oxygen from getting to the lungs and into the blood." See Acute respiratory distress syndrome, National Library of Medicine, http://www.nlm.nih.gov/medlineplus/ency/article/000103.htm (last visited May 8, 2015).

Kimmy [] has had severe and persistent pulmonary impairment which is believed to be permanent." Id. She also suffered from "organ system failure," a "severed peroneal tendon," and "severe," "chronic" pain in her right foot. Id. at 21-22.

On March 17, 2014 she and Larry initiated this action in the Circuit Court of Kanawha County, West Virginia, alleging that Kimmy's ARDS and other maladies were caused by ingesting Levaquin. See Defs.' Notice of Removal, Ex. A. The complaint, which appears to sound primarily in a theory of product liability, asserts: that Levaquin was negligently designed and manufactured, Compl. ¶¶ 22 (a), (b); that the defendants failed to adequately warn of the risks of Levaquin, Compl. ¶¶ 22 (c)-(e), 24, 26; that the defendants breached their "on-going duty of pharmaco-vigilance," Compl. ¶ 23; and that the defendants breached an express or implied warranty that "Levaquin was safe and effective treatment of infection," Compl. ¶ 25.

After receiving service of process, the defendants removed the case to this court on June 3, 2014, pursuant to 28 U.S.C. §§ 1441 and 1332. The court has subject-matter jurisdiction inasmuch as the McNairs are West Virginia citizens, Johnson & Johnson and Ortho are New Jersey corporations with their principal places of business in that state, JPI is a Pennsylvania corporation with its principal place of business in

New Jersey, and the amount in controversy exceeds the jurisdictional threshold.

Following a brief period of discovery the defendants moved for summary judgment, maintaining that their drug, Levaquin, could not possibly have caused Kimmy McNair's injuries because she received a prescription for a generic version of levofloxacin that was not manufactured or distributed by the defendants. They draw support for that proposition from two sources. First, in response to interrogatories posed by the defendants, the plaintiffs explained the source of the drugs that Kimmy ingested as follows:

> ****Reminder, the Levaquin prescription was written for Larry Brian McNair -- he was seen at CAMC Urgent Care by Dr. Mark Stephens and was diagnosed with pneumonia and had a prescription for Levaquin for 20 days but was instructed to take it for only 10 days. This was prior to Kimmy McNair becoming sick. When she became sick and sought treatment at HealthPlus Urgent Care, Dr. Downham verified that the Levaquin Plaintiff had at home was the same on [*sic*] she was going to prescribe Plaintiff for her pneumonia and instructed Plaintiff (on medical record discharge instructions) to take the Levaquin she already had at home.**

Defs.' Mot., Ex. 1 at 4. Second, the defendants point to a "Patient History Report" from a Rite-Aid Pharmacy located in Cross Lanes, West Virginia, listing the drugs prescribed to Larry McNair between January 1, 2012 and December 31, 2012. The Report shows that Larry received twenty 500 milligram tablets of

levofloxacin on March 16, 2012. Defs.' Mot., Ex. 3.[2] The levofloxacin is identified on the Report by the National Drug Code 55111028050. Id.

A National Drug Code ("NDC") is a unique number "that identifies the manufacturer and the product, among other things." Fox Rx, Inc. v. Omnicare, Inc., 38 F. Supp. 3d 398, 405 (S.D.N.Y. 2014); see also 21 U.S.C. § 360(e); 21 C.F.R. § 207.20 (requiring "drug establishments . . . that engage in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs [to] register and submit a list of every drug in commercial distribution"). The Food and Drug Administration collects NDCs in its searchable NDC Directory, which is updated daily. See National Drug Code Directory, United States Food and Drug Administration, http://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm (last visited May 8, 2015) ("Drug products are identified and reported using a unique, three-segment number, called the National Drug Code (NDC), which serves as a universal product identifier for drugs. FDA publishes the listed NDC numbers and the information submitted

[2] The plaintiffs do not object to the admissibility of this record. During a telephone conference by the court with counsel held on June 8, 2015, counsel for the plaintiffs conceded that the Patient History Report had been produced by the plaintiffs, was authentic, and was admissible.

as part of the listing information in the NDC Directory which is updated daily.").

A search in the NDC Directory for 55111028050 returns no results. As the defendants point out, however, 55111-280-50 (that is, the same number shown on the Report with the first zero omitted) is the NDC for a 500 milligram levofloxacin tablet produced by Dr. Reddy's Laboratories Limited. By contrast, all of the levofloxacin products produced by JPI have markedly different NDCs -- for example, 50458-925-50 for JPI's 500 milligram tablet.[3] Indeed, all of JPI's levofloxacin products are identified by NDCs beginning with 50458, whereas all of Dr. Reddy's levofloxacin products are identified by NDCs beginning with 55111.

In response, the plaintiffs offer no evidence that the drug Kimmy McNair ingested was produced by the defendants. Instead, they argue that "[e]ven if [the defendants are] correct that plaintiff ingested a generic, that does not and should not relieve [them] of liability" as a matter of law. See Plaintiffs' Response to Defendants' Motion for Summary Judgment ("Pls.' Resp.") at 4. More specifically, they maintain that

[3] This information can be obtained from the NDC Directory. The defendants have also filed an affidavit made by Melissa Tokosh, JPI's Director of Global Regulatory Affairs; Ms. Tokosh confirms that JPI's labeler code is 50458 and that the NDC for JPI's 500 mg Levaquin® tablet is 50458-925-50.

because generic manufacturers merely copy the initial drug design and warnings for Levaquin that the defendants created, any shortcomings in that design or in those warnings are attributable to the defendants. See id. at 6 ("Assuming that defendant [*sic*] is accurate in its determination that the levofloxacin ingested by plaintiff was a generic produced by another company, defendant researched, tested and patented levofloxacin as a new drug sold as Levaquin®. Defendant knew or should have known that generic manufacturers . . . would depend on the design of the drug and accuracy of the warning label.").

II. Legal Standard

Summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "A fact is material if it 'might affect the outcome of the suit under the governing law.'" Libertarian Party of Va. v. Judd, 718 F.3d 308, 313 (4th Cir. 2013) (quoting Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986)). And a dispute of fact is "genuine if 'a reasonable jury could return a verdict for the nonmoving party.'" Libertarian Party, 718 F.3d at 313 (quoting Dulaney v. Packaging Corp. of Am., 673 F.3d 323, 330 (4th Cir. 2012)).

"A party asserting that a fact cannot be or is genuinely disputed must support the assertion by[] citing to particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations . . . admissions, interrogatory answers, or other materials[.]" Fed. R. Civ. P. 56(c)(1)(A). The materials relied upon to establish the facts must be admissible in evidence. See Fed. R. Civ. P. 56(c)(2), (4); see also Boyer-Liberto v. Fontainebleau Corp., 752 F.3d 350, 355 (4th Cir. 2014) ("Because [Rule 56] is a mechanism to obviate trial, the facts forming the basis for a summary judgment must (1) be material; (2) be undisputed; and (3) be admissible in evidence." (citations omitted)), vacated and rev'd on other grounds ---F.3d---, 2015 WL 2116849 (4th Cir. May 7, 2015) (en banc). For example, "hearsay evidence, which is inadmissible at trial, cannot be considered on a motion for summary judgment." Md. Highways Contractors Ass'n, Inc. v. Maryland, 933 F.2d 1246, 1251 (4th Cir. 1991).

III. Discussion

The Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301, et seq., requires "drug manufacturers [to] gain approval from the United States Food and Drug Administration (FDA) before marketing any drug in interstate commerce." Mutual Pharm. Co., Inc. v. Bartlett, 133 S. Ct. 2466, 2470 (2013) (citing 21 U.S.C. § 355(a)). Under the statutory framework, the FDA may approve two kinds of applications for new drugs: a new drug application ("NDA") for brand-name drugs, 21 U.S.C. § 355(b), and an abbreviated new drug application ("ANDA") for generic versions of brand-name drugs, 21 U.S.C. § 355(j).

An NDA must include, among other things, reports and other data "relevant to an evaluation of the safety and effectiveness of the drug," 21 C.F.R. §§ 314.50(d)(2) and (5)(iv), "the labeling proposed to be used for such drug," 21 U.S.C. § 355(b)(1)(F), and "a discussion of why the benefits exceed the risks under the conditions stated in the labeling," 21 C.F.R. § 314.50(d)(5)(viii). The application will be approved only if the drug is "'safe for use' under 'the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof.'" Bartlett, 133 S. Ct. at 2471

(quoting 21 U.S.C. § 355(d)). As the Supreme Court has explained, the process is "both onerous and lengthy." Id.

After the FDA approves and officially lists a brand-name drug, and once the patent on the brand-name drug has expired, manufacturers seeking approval to bring a generic version of the drug to market may file an ANDA under the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585. In contrast to the NDA process, an ANDA may be approved "without the same level of clinical testing" if: the generic drug is (1) "chemically equivalent to the approved brand-name drug," 21 U.S.C. § 355(j)(2)(A)(ii) and (iii); (2) "'bioequivalent' to an approved brand-name drug," meaning that it has "the same 'rate and extent of absorption' as the brand name drug," 21 U.S.C. § 355(j)(2)(A)(iv) and (j)(8)(B); and if (3) "the labeling for the new drug is the same as the labeling approved for the [approved brand-name] drug," 21 U.S.C. § 355 (j)(2)(A)(v). See Bartlett, 133 S. Ct. at 2471.

"Once a drug -- whether generic or brand-name -- is approved, the manufacturer is prohibited from making any major changes to the 'qualitative or quantitative formulation of the drug product, including active ingredients, or in the specifications provided in the approved application.' Generic

manufacturers are also prohibited from making any unilateral changes to a drug's label." Id. (internal citations omitted).

This so-called "duty of sameness" imposed by federal law means that state-law failure to warn and design defect claims against generic drug producers are all but surely pre-empted. See id. at 2474-77 (holding state-law design defect claim preempted where "it was impossible for [the generic manufacturer] to comply with both its state-law duty to strengthen the warnings on [a drug's] label and its federal-law duty not to alter [the drug's] label"); PLIVA, Inc. v. Mensing, 131 S. Ct. 2567, 2580-82 (2011) (holding state-law failure to warn claims preempted where "state law imposed a duty on the [generic manufacturers] to take certain action, and federal law barred them from taking that action"); see also Drager v. PLIVA USA, Inc., 741 F.3d 470, 476 (4th Cir. 2014) ("Together, [Mensing and Bartlett] establish that under the FDCA a generic may not unilaterally change its labeling or change its design or formulation, and cannot be required to exit the market or accept state tort liability. Therefore, if a generic drug manufacturer cannot satisfy a state law duty except by taking one of these four actions, that law is preempted and of no effect."). On the other hand, because manufacturers of brand-name drugs retain the ability to unilaterally supplement their warnings pending FDA

approval, failure to warn claims against them are not preempted. Wyeth v. Levine, 555 U.S. 555, 568-73, 581 (2009) (holding that it was "not impossible for Wyeth to comply with its state and federal law obligations" where federal regulation "permitted Wyeth to unilaterally strengthen its warning, and the mere fact that the FDA approved [the brand-name drug's] label does not establish that it would have prohibited such a change").

The broad preemption of claims against generic manufacturers has created what the Supreme Court has acknowledged as an "unfortunate" quirk: plaintiffs who ingest a brand-name drug may well have a cause of action against the brand-name manufacturer, but those who ingest a generic drug with the same composition and same label as the brand-name drug have no similar recourse against the generic manufacturer. See Mensing, 131 S. Ct. at 2581 ("Had [the plaintiffs] taken Reglan, the brand-name drug prescribed by their doctors, . . . their lawsuits would not be pre-empted. But because pharmacists . . . substituted generic metoclopramide instead, federal law pre-empts these lawsuits."); see also id. at 2592 (Sotomayor, J., dissenting) ("As the majority itself admits, a drug consumer's right to compensation for inadequate warnings now turns on the happenstance of whether her pharmacist filled her prescription with a brand-name drug or a generic."). The question presented

by this case and the McNair's theory of liability is whether a plaintiff who consumes a generic may instead sue the brand-name manufacturer that produced the formula for the drug and warning label in the first instance.

The overwhelming answer is "no." Over twenty years ago, our court of appeals rejected "the contention that a name brand manufacturer's statements regarding its drug c[ould] serve as the basis for liability for injuries caused by another manufacturer's drug." Foster v. Am. Home Prods. Corp., 29 F.3d 165, 170 (4th Cir. 1994). More generally, the court concluded that there was simply "no authority" under Maryland law "for [the plaintiffs'] assertion that one manufacturer can be held liable for injuries stemming from another manufacturer's product, and [] no basis in the federal drug approval scheme for treating drug manufacturers differently from other manufacturers in product liability actions." Id. at 171.

Since then, every federal circuit court to consider the issue -- both before and after the Supreme Court rendered its holdings in Mensing and Bartlett -- has reached a similar conclusion, applying the law of several states. In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig., 756 F.3d 917, 941-54 (6th Cir. 2014) (holding that name-brand manufacturers could not be held liable for damages caused by ingestion of generic drugs

under negligent misrepresentation law of twenty-two states); Johnson v. Teva Pharm. USA, Inc., 758 F.3d 605, 616 & n.3 (5th Cir. 2014) (finding no liability against a name-brand manufacturer for injuries caused by ingestion of a generic drug under Louisiana law and observing that "[o]ur decision is consistent with other circuit decisions that have held (under the laws of several different states) that brand-name manufacturers are not liable for injuries caused by a plaintiffs ingestion of generic products"); Eckhardt v. Qualitest Pharms., Inc., 751 F.3d 674, 681–82 (5th Cir. 2014) (finding no liability under Texas Law); Lashley v. Pfizer, Inc., 750 F.3d 470, 476–78 (5th Cir. 2014) (finding no liability under Mississippi and Texas law); Schrock v. Wyeth, Inc., 727 F.3d 1273, 1281-86 (10th Cir. 2013) (finding no liability under Florida law); Guarino v. Wyeth, LLC, 719 F.3d 1245, 1252 (11th Cir. 2013) ("[T]he overwhelming national consensus -- including the decisions of every court of appeal and the vast majority of district courts around the country to consider the question -- is that a brand-name manufacturer cannot be liable for injuries caused by the ingestion of the generic form of a product."); Strayhorn v. Wyeth Pharms., Inc., 737 F.3d 378, 401–06 (6th Cir. 2013) (same under Tennessee law); Bell v. Pfizer, Inc., 716 F.3d 1087, 1093 (8th Cir. 2013) ("Because Bell never used Reglan the brand defendants manufactured, Bell cannot hold them liable under

Arkansas law."); Demahy v. Schwarz Pharma, Inc., 702 F.3d 177, 183 (5th Cir. 2012) (per curiam) (holding that Louisiana law did not recognize "claims against Wyeth and Schwarz" "because they did not manufacture the medication [the plaintiff] actually consumed"); Smith v. Wyeth, Inc., 657 F.3d 420, 423–24 (6th Cir. 2011) (rejecting the argument, under Kentucky law, "that the name-brand defendants' liability stems from the fact that the regulatory structure governing name-brand and generic drugs makes it foreseeable that patients and their physicians will rely on the name-brand labels to use and prescribe generic drugs").

There is no reason to think the outcome would be any different under West Virginia law. As this court has previously explained, "Product liability law in West Virginia allows for recovery when the plaintiff can prove that 'a product was defective when it left the manufacturer and the defective product was the proximate cause of the plaintiff's injuries.'" Meade v. Parsley, No. No.09-388, 2009 WL 3806716, at *3 (S.D. W. Va. Nov. 13, 2009) (Copenhaver, J.) (quoting Dunn v. Kanawha Cnty. Bd. of Educ., 459 S.E.2d 151, 157 (W. Va. 1995)). As a result, because the defendants did not manufacture the product that Kimmy McNair ingested, "there is no proximate cause," and no basis upon which to hold them liable. Id.; see also In re

Darvocet, 756 F.3d at 953-54 ("Guided by the Meade court, we predict that the West Virginia Supreme Court of Appeals would construe Plaintiffs' misrepresentation claims as product liability claims that fail for lack of product identification, or alternatively that the Brand Manufacturers did not owe Plaintiffs a duty that could give rise to liability."); Michael v. Wyeth, LLC, No. 04-435, 2011 WL 2011485, at *2 (S.D. W. Va. May 23, 2011) (Copenhaver, J.) ("To succeed in a products liability action, a plaintiff must show that the defendant manufactured the product that injured her. And so, . . . Upjohn is not a proper party to this action if plaintiff did not ingest any of its drugs." (internal citations omitted)).

The plaintiffs' breach of express or implied warranty claims fare no better. In West Virginia, "a warranty that the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind," W. Va. Code § 46-2-314(1), and if the seller knows at the time of contracting that the goods will be used for a particular purpose, "there is unless excluded or modified . . . an implied warranty that the goods shall be fit for such purpose," id. § 46-2-315. In a similar vein, "[a]ny affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an

express warranty that the goods shall conform to the affirmation or promise." Id. § 46-2-313. But Kimmy McNair ingested a generic version of levofloxacin, and the defendants consequently were not the "sellers" of the goods at issue. They thus made no warranty of any kind about the specific product that she (or Larry) purchased and ultimately ingested.

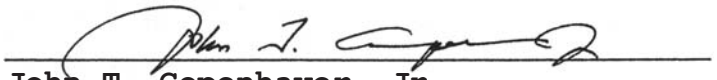
In sum, because Kimmy McNair did not ingest name-brand Levaquin, the defendants did not manufacture or sell the product that allegedly injured her. Accordingly, they are not susceptible to the plaintiffs' claims for product liability and breach of warranty.

IV. Conclusion

For the foregoing reasons, the defendants' motion for summary judgment is granted.

The Clerk is requested to transmit a copy of this order to all counsel of record and any unrepresented parties.

ENTER: June 26, 2015



John T. Copenhaver, Jr.
United States District Judge